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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re Bard IVC Filters Products
Liability Litigation

No. MD-15-02641-PHX-DGC

Case No. 2:16-cv-00853-DGC

DEBRA MULKEY, an individual,
Plaintiff,

v.

C.R. BARD, INC., a New Jersey
corporation and BARD PERIPHERAL
VASCULAR, an Arizona corporation,

Defendants.

**PLAINTIFF DEBRA MULKEY'S
OPPOSITION TO DEFENDANTS'
MOTION FOR SUMMARY JUDGMENT
AND MEMORANDUM IN SUPPORT**

1 I. INTRODUCTION

2 On April 11, 2012, Plaintiff Debra Mulkey was implanted with a Bard Eclipse
3 filter. The filter was defective and, as such, after placement the filter failed and injured
4 her by tilting, becoming embedded in her vena cava, penetrating her vena cava and
5 surrounding organs and structures (including the duodenum and spine), and fracturing.
6 Additionally, one of the perforating struts is close to penetrating her aorta.

7 Bard moved for summary judgment on all of plaintiff's claims based on
8 Kentucky's one-year statute of limitations¹, as well as on the following individual counts:
9 Strict liability and Negligent Failure-to-Warn (Count II and VII); Negligence *Per Se*
10 (Count IX); Breach of implied warranty (Count XI); Negligent and fraudulent
11 misrepresentation/concealment (Counts VIII, XII, XIII); Violation of the Kentucky
12 Consumer Protection Act ("KCPA") (Count XIV); and Failure to recall/retrofit (Count
13 VI)².

14 Plaintiff withdraws her claim for breach of implied warranty (Count XI), but
15 opposes Bard's motion as to all remaining issues. On each of these claims, when
16 construed in a light most favorable to Ms. Mulkey, there are issues of fact that are both
17 material and genuine. *Bray v. Husted*, 11 F. Supp. 3d 854, 858–59 (E.D. Ky. 2014). A
18 jury should resolve these issues.

19 II. SUMMARY JUDGMENT STANDARD

20 Summary judgment is appropriate when no genuine issues of material fact exist
21 and a party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). In applying

22 ¹ This case was chosen and endorsed by Bard for inclusion in the bellwether discovery
23 pool, and ultimately as one of the five bellwether trial cases. Bard put forth this case as
24 representative of the larger group of cases pending in the MDL. Confusingly, Bard now
25 seeks summary judgment not on a legal issue applicable to multiple cases in the MDL, but
26 rather on a narrow, case specific issue that would render this case inappropriate as a
27 bellwether selection. Bard cannot truly believe this case is barred by the statute of
limitations, or it would not have represented to this Court that this case was a proper
bellwether selection.

28 ² Defendants incorrectly characterize this as a "post-sale duty to warn claim." Plaintiff
asserts a claim for post-sale duty to recall and failure to retrofit as addressed below.

1 this standard, “[t]he evidence of the non-movant is to be believed, and all justifiable
 2 inferences are to be drawn in his favor.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242,
 3 255 (1986). Thus, if a reasonable trier of fact could find in favor of the non-moving party,
 4 summary judgment is improper. *Id.* at 248.

5 **III. PLAINTIFF’S CLAIMS ARE NOT BARRED BY THE STATUTE OF** 6 **LIMITATIONS**

7 Under Kentucky law, a personal injury product liability action must be commenced
 8 within one year after the cause of action accrued. Ky. Rev. Stat. Ann. § 413.140(1)(a).
 9 However, Kentucky law provides a “discovery rule” exception, which tolled the statute of
 10 limitations in this case. *See, e.g., Wiseman v. Alliant Hospitals, Inc.*, 37 S.W.3d 709 (Ky.
 11 2000).

12 **a. Debra Mulkey did not discover she was “harmed”, let alone “injured”,** 13 **by her Bard IVC filter until October 2015.**

14 “Under the ‘discovery rule,’ a cause of action will not accrue until the plaintiff
 15 discovers (or in the exercise of reasonable diligence should have discovered) not only that
 16 he has been injured, but also that this injury may have been caused by the defendant’s
 17 conduct.” *Fluke Corp. v. LeMaster*, 306 S.W.3d 55, 60 (Ky. 2010). The “knowledge
 18 necessary to trigger the statute is two-pronged; one must know: (1) he has been wronged;
 19 and (2) by whom the wrong has been committed.” *Wiseman*, 37 S.W.3d at 712. In
 20 constructing knowledge a court must give special consideration to the patient’s
 21 perspective because “[o]ne who possesses no medical knowledge should not be held
 22 responsible for discovering an injury based on the wrongful act” *Wiseman*, 37
 23 S.W.3d at 712-13.

24 Kentucky Law makes an important distinction between discovery of “harm” versus
 25 discovery of “injury.” *Wiseman*, 37 S.W.3d at 712. In order to trigger the running of the
 26 statute of limitations, a plaintiff must have “actual or constructive knowledge of the
 27 injury”, not just the harm. *Id.* Injury is more than just the loss of health, it is the
 28 “invasion of any legally protected interest of another.” *Id.*

1 Dr. Roderick Tompkins implanted a Bard Eclipse IVC filter in Ms. Mulkey on
 2 April 11, 2012, [REDACTED]. (OSOF ¶¶ 191-193). Prior to
 3 implant, Dr. Tompkins told Ms. Mulkey that the Bard Eclipse filter could be removed or
 4 safely left in permanently. (OSOF ¶ 201). Thus, Ms. Mulkey believed going into her
 5 surgery that the filter was safe for retrieval or to be left in permanently.

6 Following her [REDACTED], Dr. Tompkins sent Ms. Mulkey to have her Eclipse
 7 IVC filter removed. (OSOF ¶ 241). On October 4, 2012, Dr. Pho Nguyen unsuccessfully
 8 attempted to remove Ms. Mulkey's filter. (OSOF ¶ 242-245). It is this unsuccessful
 9 retrieval attempt that Bard claims triggered the running of Ms. Mulkey's statute of
 10 limitations. (Def. Mot. at 6). Bard is wrong. Based on the record evidence, Ms. Mulkey
 11 did not, and could not be expected to, discover at the time of her failed retrieval that she
 12 had been harmed, let alone injured (i.e. her legal rights had been invaded by Bard), by her
 13 Bard filter or that Bard had wronged her:

- 14 • The day of surgery, Dr. Nguyen recommended to Ms. Mulkey that the IVC
 15 filter be left in the body. (OSOF ¶ 244).
- 16 • Ms. Mulkey was not informed that her filter was tilted at the time of the
 17 unsuccessful removal attempt. (OSOF ¶ 247).
- 18 • Dr. Nguyen never told Ms. Mulkey there was anything wrong with the IVC
 19 filter. (OSOF ¶ 248).
- 20 • Ms. Mulkey was not informed there was any problem with leaving the
 21 Eclipse filter in her body; in fact, Dr. Tompkins informed her it could be left
 22 in the body permanently. (OSOF ¶¶ 249-250).
- 23 • Dr. Tompkins never told Ms. Mulkey her IVC filter was defective. (OSOF
 24 ¶ 251).
- 25 • Dr. Tompkins never told Ms. Mulkey Bard had injured her or caused her
 26 harm. (OSOF ¶ 252).
- 27 • Dr. Tompkins never told Ms. Mulkey her IVC filter was unsafe. (OSOF ¶
 28 253).
- Ms. Mulkey did not believe she had been injured or anything was wrong
 with her filter. (OSOF ¶¶ 246, 254).
- No health care provider ever told Ms. Mulkey that any of her symptoms
 related to bodily injury were related to the Bard IVC filter. (OSOF ¶ 257).
- Ms. Mulkey did not believe there was anything defective about her filter.
 (OSOF ¶ 255).

- Ms. Mulkey did not believe she had been wronged by the manufacturer of the IVC filter, Bard. (OSOF ¶ 256).

It was not until October of 2015 that Ms. Mulkey found out she had been harmed and injured by her Eclipse filter, and wronged by Bard:

- She did not have any concerns about the filter until late 2015, when she found out people were having problems with their IVC filters. (OSOF ¶ 258).
- In the fall of 2015, Ms. Mulkey saw television and internet advertisements about IVC filters. (OSOF ¶ 259). When Ms. Mulkey saw these ads, she became concerned about her filter. (OSOF ¶ 260). At that time, in late 2015, Ms. Mulkey first realized that she may have been wronged by Bard. (OSOF ¶ 261).
- It was not until October 2015 that Ms. Mulkey learned that a defect in the IVC filter might be the reason that it could not be removed from her body. (OSOF ¶ 262).

In *Wiseman*, a case instructive to ours, the plaintiff underwent a dilatation and curettage (“D & C”) procedure. *Wiseman*, 37 S.W.3d at 711. Immediately after the surgery, the plaintiff began experiencing pain in her coccyx but was informed by the doctor that the surgery could not be the source of the pain. Over the next several years, the plaintiff continued to experience pain in her coccyx, and multiple physicians diagnosed her with a broken tailbone. Almost seven years after her initial D & C, the plaintiff developed a cyst that ultimately required surgery. During this surgery, the doctor “discovered a piece of a metal ... under the surface of the skin” left inside of the plaintiff during her D & C. *Id.*

The Kentucky Supreme Court rejected the argument that her claim—brought seven years after the initial surgery—was barred by the statute of limitations. The Court explained that although the plaintiff experienced *harm* immediately after her first surgery, this “discovery of harm” was insufficient to start the limitations period. “Harm . . . might be the loss of health following medical treatment.” *Wiseman*, 37 S.W.3d at 712. Injury, on the other hand, is the “invasion of any legally protected interest of another.” *Id.* Thus, although the plaintiff in *Wiseman* discovered her harm almost immediately, she could not have discovered her injury until the metal instrument was located inside of her.

1 In our case, like in *Wiseman*, Ms. Mulkey arguably had constructive knowledge
 2 that she had been *harmed* at the time of the unsuccessful removal (although unlikely based
 3 on the evidence), but she clearly did not have knowledge she was *injured* or that she had
 4 been *wronged* by Bard. As set forth above, none of her physicians ever told her this;
 5 instead, they told her the filter was safe to be left in permanently and recommended that
 6 she do so. Nor did any physician ever tell her the filter was defectively designed, the filter
 7 had injured her, or that she had been wronged by Bard.

8 Based on the foregoing, Ms. Mulkey's statute of limitations did not begin running
 9 until October of 2015, and Defendants' Motion should be denied.

10 **b. Ms. Mulkey had no duty to inquire into the safety of her IVC filter**
 11 **because she lacked actual or constructive knowledge it had harmed or**
 12 **injured her, and she was told it could remain permanently in her body.**

13 Bard cites *Fluke*³ for the proposition that "plaintiffs have a duty to inquire into the
 14 safety of products where it is apparent from the facts that the product may have been a
 15 potential cause of an injury," and "[a]n injured party has an affirmative duty to use
 16 diligence in discovering the cause of action within the limitations period. Any fact that
 17 should excite his suspicion is the same as actual knowledge of this entire claim."

18 In *Fluke Corp.*, three electrical contractors were injured by an explosion that
 19 occurred while they were working on a breaker that their voltage meter inaccurately
 20 showed had no electricity flowing to. *Fluke Corp.*, 306 S.W.3d at 60. The court held that
 21 even though the contractors had not previously heard of voltage meters malfunctioning,
 22 "they should have reasonably suspected that the voltage meter was not working properly
 23 and investigated this possibility." *Id.* For this reason, the discovery rule had no
 24 application in the case. *Id.* "[T]he discovery rule is available only in cases where the fact
 25 of injury or offending instrumentality is not immediately evident or discoverable with the
 26 exercise of reasonable diligence, such as in cases of . . . or latent injuries or illnesses." *Id.*

27 _____
 28 ³ Defendants also cite *Asher v. Unarco Material Handling*, 596 F.3d 313, 321-22 (6th Cir. 2010) and
Caudill v. Arnett, 481 S.W.2d 668, 669 (Ky. 1972). These cases are distinguishable from ours for the
 same reasons as *Fluke Corp. v. LeMaster*, 306 S.W.3d 55, 60 (Ky. 2010).

1 *Fluke* is distinguishable from our case because the plaintiffs did not dispute that
 2 their injuries were immediately apparent. *Id.* at 61. To the contrary, they were blatantly,
 3 obviously and instantaneously injured by an explosion. In direct contrast to the *Fluke*
 4 plaintiffs' injury is the latent injury sustained by Ms. Mulkey. While aware that the filter
 5 had grown into her vena cava and could not be retrieved, she was not informed and could
 6 not reasonably have learned that she was harmed, let alone injured, by this fact. (OSOF
 7 ¶¶ 201, 244-258). A reasonable patient would expect that if he or she were injured as a
 8 result of an IVC filter, a physician would discuss this injury with him or her. Instead, Dr.
 9 Nguyen told Ms. Mulkey at the time of her unsuccessful retrieval procedure that the IVC
 10 filter could remain in place. (OSOF ¶ 244, 249-250). She was not told that there was any
 11 risk or danger to keeping the IVC filter in place; in fact, she was told the filter was safe to
 12 be left in permanently. (OSOF ¶ 201, 244, 249-250, 253). She was not told that she had
 13 sustained any injury or damage from the IVC filter. (OSOF ¶ 246-258). She was not told
 14 that the IVC filter was defective or that Bard had wronged her. (OSOF ¶ 248, 251-257).

15 Moreover, no health care provider ever told Ms. Mulkey that she was injured by
 16 her IVC filter. (OSOF ¶ 246-247, 252, 254). This is an important distinction from the
 17 unpublished decision on which Bard relies, *In re Mentor Corp. ObTape Transobturator*
 18 *Sling Products Liability Litigation*, Nos. 2016 WL 873647 (M.D. Ga. March 4, 2016).
 19 The plaintiff in *Mentor* brought a product liability action based on design and
 20 manufacturing defects with ObTape, a suburethral sling product. *Id.* at *1. During her
 21 treatment, the plaintiff was twice diagnosed by her treating physician with a localized
 22 abscess over her ObTape incision. Given the location of the abscess, her treating
 23 physician believed that the abscesses were caused by the ObTape. Because the plaintiff
 24 had been treated for two abscesses that her doctor believed were caused by the ObTape,
 25 and plaintiff presented no evidence that her doctors told her that her injuries were *not*
 26 connected to the ObTape, the court held that plaintiff "had enough information to know of
 27 a connection between ObTape and at least some of her injuries." *Id.* at *2 (emphasis
 28 added). There is no evidence that any health care provider told Ms. Mulkey that she was

1 injured by the IVC filter. Ms. Mulkey’s physicians did just the opposite – they reassured
 2 her that the IVC filter could remain permanently in her body. (OSOF ¶¶ 201, 244, 249-
 3 250).

4 Our case is analogous to *Roberts v. Stryker Corp.*, 2011 WL 2912697 (E.D.Ky.
 5 July 18, 2011). The *Roberts* plaintiff underwent shoulder surgery and alleged that as a
 6 result of the pain pump he developed a condition known as chondrolysis. *Id.* at *1. The
 7 Eastern District of Kentucky rejected defendants’ argument that the discovery rule did not
 8 apply and distinguished *Fluke*. *Id.* at *2. The court identified that the *Fluke* plaintiffs’
 9 injuries were “immediately apparent” and they had a duty to investigate. By contrast, the
 10 *Roberts* plaintiff “had prior shoulder problems and continued having shoulder problems
 11 after the surgery at issue ... [so] had absolutely no reason to associate those problems with
 12 the use of a pain pump or to suspect the pain pump was somehow defective.” *Id.* at *3.
 13 Similarly, Ms. Mulkey had no reason to suspect her IVC filter was defective or to believe
 14 that she had suffered injury as a result of the IVC filter remaining in her body. (OSOF ¶¶
 15 201, 244-258). Given these facts, Ms. Mulkey had no duty to investigate her claim until
 16 October 2015, when she first saw television advertisements causing her to become
 17 concerned about her IVC filter. (OSOF ¶ 258-262). This is when her cause of action
 18 accrued, and Defendants’ Motion should be denied.

19 **c. Under Kentucky law, when there is a factual issue upon which the**
 20 **application of the statute of limitations depends, it is proper to submit**
 21 **the question to the jury.**

22 At the very least, in light of the various inferences that a factfinder might make as
 23 to Ms. Mulkey’s knowledge and state of mind, there is a factual dispute as to whether Ms.
 24 Mulkey knew or should have known that she had a claim as of Dr. Nguyen’s unsuccessful
 25 removal attempt on October 4, 2012. In Kentucky, although the validity of the defense of
 26 statute of limitations is determined by the court as a matter of law, where “there is a
 27 factual issue upon which the application of the statute depends, it is proper to submit the
 28 question to the jury.” *Elam v. Menzies*, 594 F.3d 463 (6th Cir. 2010) (citing *Lynn Mining*
Co. v. Kelly, 394 S.W.2d 755, 759 (Ky. 1965)); *see also* 13 Ky. Prac. Tort Law § 10:39

(2009). Both Kentucky law and federal procedural law used in diversity cases specify that disputed issues of fact respecting the running of a statute of limitations should be resolved by a jury. *Id.* Additionally, on a motion for summary judgment this Court must construe all facts in a light most favorable to the non-moving party. *Bray v. Husted*, 11 F. Supp. 3d 854, 858–59 (E.D. Ky. 2014). *See Van Landingham v. Georgia–Pac. Corp.*, 2009 WL 2475258, *3, Case No. 2007–CA–002601–MR (Ky. Ct. App. Aug. 14, 2009) (unpublished) (“It is not within the province of this [C]ourt to determine whether [the plaintiff] knew or should have known that he was injured by [defendant’s] malpractice.”). As the Sixth Circuit noted in *Elam*, “[t]he driving force in our decision is the summary judgment standard, which requires us to draw all reasonable inferences in favor of [plaintiff].”

Based on the foregoing, this Court should at the very least allow the jury to determine whether Ms. Mulkey knew or should have known she sustained injury on October 4, 2012, the date of the unsuccessful filter retrieval attempt.

IV. MS. MULKEY WITHDRAWS HER BREACH OF IMPLIED WARRANTY CLAIM (COUNT XI).

Plaintiff hereby withdraws Count XI, Breach of Implied Warranty, and requests that the Court decline to rule on this claim as moot.

V. BARD’S WARNINGS WERE INADEQUATE AND WERE THE PROXIMATE CAUSE OF MS. MULKEY’S INJURIES.

a. Bard did not provide legally adequate warnings to the learned intermediary, Dr. Tompkins, of dangers known to it prior to Ms. Mulkey being implanted with the Eclipse Filter.

“Kentucky law imposes a general duty on manufacturers and suppliers to warn of dangers known to them but not known to persons whose use of the product can reasonably be anticipated.” *West v. KKI, LLC*, 300 S.W.3d 184, 192 (Ky. App. 2008) (citing *Watters v. TSR, Inc.*, 904 F.2d 378, 381 (6th Cir. 1990)). Failure to warn requires: (1) the manufacturer failed to provide his prescribing physician with adequate warnings about the risks of which it knew or should have known; and (2) the inadequate warnings were the proximate cause of the plaintiff’s injuries. *Estate of DeMoss by and*

1 through *DeMoss v. Eli Lilly & Co.*, 2017 WL 561337, at *4 (W.D. Ky. 2017) (citing
 2 *Prather*, 960 F. Supp. 2d at 708-09). Even though the manufacturer's duty to warn runs
 3 only to the learned intermediary, that warning must still be adequate. *Larkin v. Pfizer,*
 4 *Inc.*, 153 S.W.3d 758, 764 (Ky. 2004) (citing *Pittman v. Upjohn Co.*, 890 S.W.2d 425,
 5 429 (Tenn. 1994) (“[T]he learned intermediary doctrine does not shield a [defendant]
 6 from liability for inadequate warnings to the physician.”)). An adequate warning must be
 7 “sufficient to apprise the general practitioner as well as the unusually sophisticated
 8 medical man of the dangerous propensities of the” drug or device. *Larkin*, 153 S.W.3d at
 9 770. The warning must be fair and adequate, to the end that the user, by the exercise of
 10 reasonable care on his own part, shall have a fair and adequate notice of the possible
 11 consequences of use or even misuse. *Post v. American Cleaning Equipment Corp.*,
 12 437 S.W.2d 516, 520 (Ky. 1968).

13 Bard contends it is entitled to summary judgment because the Eclipse IFU included
 14 generic references to filter tilt, migration, fracture, perforation and inability to retrieve,
 15 and those “warnings” were adequate. (Def. Mot. at 11-12). However, Bard's warnings
 16 were inadequate because the Eclipse IFU did not inform physicians that the rates and
 17 severity of complications with Bard filters were greater than those of competitor devices
 18 and the SNF, information known to Bard but not physicians, and thus the learned
 19 intermediary doctrine does not apply.⁴

20 This was confirmed by Dr. Tompkins who testified the Bard Eclipse IFU did not
 21 warn of an increased risk of movement, migration, or tilt with Bard filters as compared
 22 with any other filter, including the SNF and competitor filters. (OSOF ¶ 223-225). He

23 ⁴ Defendants misstate the finding of *Tipton v. Michelin Tire Co.*, which does not address
 24 whether there is a duty to warn of safer products in the market. *Tipton* merely states that
 25 in Kentucky, a manufacturer is not required to make a product as good as others make "as
 26 long as it is reasonably safe." 101 F.3d 1145, 1149 (6th Cir. 1996) citing *Jones v.*
 27 *Hutchinson Manufacturing, Inc.*, 502 S.W.2d 66, 69 (Ky.1973). "Another way of putting
 28 'reasonably safe,' as expressed in *Jones*, is whether the product was unreasonably unsafe
 or dangerous." *Id.* As detailed herein, the Eclipse filter was “unreasonably unsafe.” Bard
 was aware of the increased risks and dangers of the Eclipse, including the increased risk
 of caudal migration, and had a duty to warn of these risks.

1 further testified he would have wanted to know about the increased risk of migration over
 2 other filters because it would have affected his prescribing habits, and he wouldn't have
 3 used the filter. (OSOF ¶ 226-228). Dr. Tompkins agreed there were risks and problems
 4 with Bard's filters that Bard did not tell him about. (OSOF ¶ 230).

5 At the time Ms. Mulkey was implanted with her Eclipse filter, Bard knew and
 6 did not include in the IFU or otherwise warn physicians that, for example (*see* the full
 7 OSOF for a more thorough statement of Bard's countless failures to warn):

- 8 • By May 2004, Bard determined that the Recovery had a statistically significant
 9 higher rate of complications than the SNF and competitor filters. (OSOF ¶ 49.c-
 d).
- 10 • By July 9, 2004, Bard determined that the Recovery had a fracture rate that was
 11 tens of times higher than other filters on the market. (OSOF ¶ 49.a.).
- 12 • By December 2004, Bard determined that the Recovery filter had reporting rates of
 13 complications as compared to all other filters, including the SNF, as follows:
 14 o for deaths, 4.6 times higher;
 15 o for migrations, 4.4 times;
 16 o for IVC perforations, 4.1 times higher; and
 17 o for fractures, 5.3 higher times higher.

18 Bard concluded that "[t]hese differences were all statistically significant." (OSOF
 19 ¶ 57).

- 20 • According to Bard's current Quality Engineering Manager for New Product
 21 Development, Natalie Wong, the Recovery was worse than the SNF with
 22 regard to filter-related deaths and filter fracture. (OSOF ¶ 38).
- 23 • The Recovery filter was the predicate device and platform for the G2 filter.
 24 (OSOF ¶ 62).
- 25 • The Eclipse is essentially identical to the G2. (OSOF ¶¶ 96, 101-102).
- 26 • In terms of caudal migration, the design of the Eclipse was the same as the
 27 G2/G2X. (OSOF ¶ 102, 108-109).
- 28 • There was no evidence that the Eclipse improved resistance to fracture, migration
 or corrosion over the G2/G2X. (OSOF ¶ 108).
- By November 2005, Bard was aware of the fact that the G2 filter had a perforation
 rate that was approximately 10 times that of the SNF. [OSOF ¶ 77-78]. Bard's
 own Corporate Clinical Affairs Director, Dr. Ciavarella questioned why Bard was
 even selling the G2 Filter that had been approved when the SNF "has virtually no
 complaints associated with it." (OSOF ¶ 80).

- 1 • By February 15, 2006, a Bard Health Hazard Evaluation characterized the
2 “Severity” of the migration problems with the G2 as “Critical” and stated that “the
3 cases reported in the literature have not been as frequently associated with
4 significant caudal movement (such as down to the iliac veins) or filter tilting and
5 malpositioning as have been reported for the G2 filter.” (OSOF ¶ 82).
- 6 • In April 2006 Bard’s own internal design failure modes effects analysis found
7 the G2 to pose an “unacceptable risk.” (OSOF ¶ 82). Bard did not inform
8 physicians of this unacceptable risk. (OSOF ¶ 115.g., 119).
- 9 • By mid-2006, Bard new the G2 had an issue with caudal migration and tilt caused
10 by design problems with the G2 that needed to be fixed. (OSOF ¶ 81). Bard never
11 told physicians this was ongoing.
- 12 • Despite Bard’s concern about the need to improve the caudal migration resistance
13 of the G2 Filter line, the Product Performance Specification for the Eclipse
14 included no performance standard or testing relating to caudal migration resistance.
15 (OSOF ¶ 109).
- 16 • By June 2011, Bard was aware that the Eclipse, after only a little over a year on
17 the market, fractured over 3 ½ times as often as the SNF. (OSOF ¶ 114).
- 18 • During the time period it was selling the Eclipse, Bard was working to develop
19 its Denali filter. (OSOF ¶ 106). This was to correct the design defects known to
20 Bard with its existing retrievable filters.
- 21 • Caudal migration of filters leads to tilt, perforation, irretrievability and fracture.
22 (OSOF ¶ 99), all of which were injuries/complications suffered by Ms. Mulkey
23 (OSOF ¶ 263).

24 Bard knew of these dangers and failed to provide Dr. Tompkins with adequate
25 notice of the possible consequences of using the Eclipse. *See Post v. Am. Cleaning*
26 *Equipment Corp.*, 437 S.W.2d 516, 520 (Ky. 1968). Simply mentioning certain
27 complications was insufficient. *See Cisson v. C.R. Bard, Inc.*, No. 2:11-CV-00195,
28 2013 WL 5700513, at *7 (S.D. W. Va. Oct. 18, 2013), *aff’d sub nom. In re C.R. Bard,*
Inc., MDL No. 2187, Pelvic Repair Sys. Prod. Liab. Litig., 810 F.3d 913 (4th Cir. 2016)
(holding that where Bard warned of complications but not of rates or severity, it was a
jury question as to whether the warnings were adequate); *see also Cason v. C.R. Bard,*
Inc., 2015 WL 9913809 (N.D. Ga. Feb. 9, 2015)(finding a “genuine issue of fact” for the
jury as to whether Bard’s warnings were adequate and should have included that the G2
experienced complications at significantly higher rates than other manufacturer’s IVC
filters and the SNF).

Although not based on Kentucky law, *Cisson* is informative here as Bard previously lost the exact argument it now makes. 2013 WL 5700513. There, in a bellwether case in the Bard transvaginal mesh litigation, the plaintiff contended that Bard's warnings for the medical device "failed to warn about the rate and severity of" the complications for the device. *Id.* at *7. Bard argued, as it does here, "that its duty was limited to warning about possible complications, not their rate or severity" and its warnings were adequate because they included the injuries the plaintiff suffered. *Id.* The court found, however, "Bard's warnings were adequate as a matter of law only if 'a reasonable jury would not have a legally sufficient evidentiary basis' to find against Bard." *Id.* at *8. The court identified evidence that Bard knew its device "created a higher risk of complications" and concluded that there was "sufficient evidence to create a jury question as to whether Bard's warning was adequate." *Id.* In our case, just as in *Cisson*, Bard's knowledge that its IVCs, including the Eclipse, created a higher risk of complications than its competitors and the SNF creates a jury question as to whether its warning at issue was adequate.

b. Bard's failure to warn of the increased risks with the Eclipse was the proximate cause of plaintiff's injuries.

Bard also claims that Ms. Mulkey has not established its failure to warn was the proximate cause of her injuries. In the duty to warn context, the question is: "Could an adequate warning have prevented Ms. Mulkey's injury?" *See Tingey v. Radionics*, 193 Fed. Appx. 747, 759 (2006). Bard incorrectly argues Dr. Tompkins never testified it is probable he would have decided against using the Eclipse filter if he had been given different and additional about that Filter. To the contrary,

- Dr. Tompkins wanted to use the safest available IVC filter that would establish the goal of stopping pulmonary embolisms. (OSOF ¶ 232).
- There were risks and problems with Bard's filters that Bard did not tell Dr. Tompkins about. (OSOF ¶ 230; *see also* discussion above).
- At the time that Ms. Mulkey's filter was implanted, Dr. Tompkins did not expect it to tilt, become irretrievable, or perforate Ms. Mulkey's vena cava or other organs. (OSOF ¶¶ 234-235). If Dr. Tompkins had expected these issues to occur, he would not have used the filter. (OSOF ¶ 236).

- 1 • If the Eclipse had a significantly increased risk of migration over other filters, that
2 information would affect Dr. Tompkins' prescribing habits, and he wouldn't use
the filter. (OSOF ¶ 228).
- 3 • Dr. Tompkins expected Bard to notify him immediately if it was aware of problems
4 with the design of one of its filters that was causing complications and problems
5 for patients, or if it was in the process of redesigning its filter to reduce
complications. Dr. Tompkins wanted to know this information because it would
6 help him decide whether he even wanted to use the filter. (OSOF ¶ 229).
- 7 • Dr. Tompkins would not have implanted the Eclipse filters had he been informed
8 that there were deaths occurring concurrently. (OSOF ¶ 233).

9 As Dr. Tompkins testified, if he had received adequate warnings, he would not
10 have implanted the Eclipse. Adequate warnings would have prevented Ms. Mulkey's
11 injury, but at the very least the jury should get to make that decision.

12 **VI. MS. MULKEY'S MISREPRESENTATION AND CONCEALMENT
13 CLAIMS SHOULD GO FORWARD BECAUSE DR. TOMPKINS RELIED
14 UPON THE ECLIPSE IFU IN HIS CARE OF MS. MULKEY, AND SHE
15 RELIED UPON INFORMATION FROM DR. TOMPKINS.**

16 Bard maintains that Ms. Mulkey's misrepresentation and concealment claims fail
17 because she did not receive brochures and did not know that Bard was the manufacturer of
18 her IVC filter. This argument ignores Dr. Tompkins' reliance on information from Bard
19 in his care and treatment of Ms. Mulkey. Dr. Tompkins had seen the IFU and passed
20 along pertinent warnings from the IFU to his patients. (OSOF ¶¶ 197-198, 222). Dr.
21 Tompkins was unaware of certain risks and problems with Bard's filters, and he would
22 not have implanted the Eclipse filters if he had been informed of those risks—including
23 deaths and increased risk of complications over other filters. (OSOF ¶¶ 228-229, 230,
24 233-236). These increased risks were not included in the IFU. (OSOF ¶ 72, 74, 223).
25 Moreover, Dr. Tompkins testified that if Bard had made him aware of the significant
26 problems and safety issues with its IVC filters, which he expected them to do, he would
27 have passed that information on to his patients – i.e. Ms. Mulkey. (OSOF 222, 227,
28 231). Lastly, Bard did not inform physicians that its product performance testing for the
Eclipse filter did not address caudal migration resistance – despite Bard being aware for
years prior to that testing of the need to address that issue. (OSOF ¶ 109). These facts
support a claim for fraudulent concealment.

1 Bard also made affirmative misrepresentations about its filters. As early as 2004
 2 Bard was aware of the increased complication risks and design problems with the Eclipse
 3 and its predecessor devices, the Recovery, G2 and G2X Filters, as discussed in subsection
 4 V(a), *supra*. Despite this, Bard promoted the Eclipse to be more resistant to fracture.
 5 (OSOF ¶ 107). Bard represented the Eclipse Filter as designed to be safe for use as a
 6 permanent implant. (OSOF ¶ 111-112). Bard also promoted the Eclipse as having
 7 enhancements to a number of complications seen in prior iterations. (OSOF ¶ 107). As
 8 detailed in the OSOF and discussed *infra*, Bard misrepresented all of these facts.

9 In this case, Dr. Tompkins acted in reliance on Bard's misrepresentations and
 10 concealments regarding the Eclipse's increased complication rates when he recommended
 11 to Ms. Mulkey that she proceed with implantation of that filter. *See supra*. Ms. Mulkey
 12 then followed and relied on Dr. Tompkins' professional medical advice by agreeing to
 13 insertion of the IVC filter. (OSOF ¶ 194). Dr. Tompkins passes along pertinent warnings
 14 in the IFU to his patients. (OSOF ¶ 222). There were risks and problems with Bard's
 15 filters that Bard did not tell Dr. Tompkins about. (OSOF ¶ 230; *see also* discussion
 16 above). Ms. Mulkey was induced into undergoing implantation of the IVC filter because
 17 of the Bard's failure to disclosure material facts, including, but not limited to, the Eclipse
 18 device's greater risk of movement, migration, or tilt.

19 Because Ms. Mulkey and her physician relied on Bard's material
 20 misrepresentations in choosing to her Eclipse filter implanted, a valid claim for negligent
 21 or fraudulent misrepresentation exists.

22 **VII. KENTUCKY LAW RECOGNIZES POST-SALE DUTIES FOR** 23 **DEFECTIVE PRODUCTS AND FOR NEGLIGENT PERFORMANCE OF** **RETROFIT CAMPAIGNS.**

24 **a. Plaintiff's Negligent Post-Sale Failure to Recall/Retrofit Claim is** 25 **recognized because the Eclipse filter was defective at the time it was** **sold.**

26 Bard relies upon *Ostendorf v. Clark Equipment Co.*, 122 S.W.3d 530, 539 (Ky.
 27 2003), for its contention that Kentucky does not recognize a post-sale failure to recall
 28 and/or retrofit a product. However, *Ostendorf* held only that Kentucky does not recognize

1 a common-law duty by a seller to retrofit a product *that was not defective at the time it*
 2 *was sold*. *Id.* at 533 (emphasis added).

3 The Bard Eclipse was defective at the time it was sold. When the Eclipse Filter
 4 was cleared for market in January 2010 it contained only a minor design modification
 5 added purely for marketing purposes and was not intended to overcome any of the serious
 6 complications of the prior G2/G2X Filter line. (OSOF ¶¶ 102, 105, 108). There was no
 7 evidence that the Eclipse improved resistance to fracture, migration, or corrosion and, in
 8 fact, the design of the Eclipse was the same as the G2 and the G2X in terms of caudal
 9 migration. (OSOF ¶¶ 102, 108). A caudal migration risk that Bard had internally deemed
 10 “unacceptable” in 2006 – nearly 5 years before Ms. Mulkey received her Eclipse IVC
 11 filter. (OSOF ¶ 82). Moreover, Bard had been aware since no later than the beginning of
 12 2006 of the need to address caudal migration, yet had no product performance
 13 specification on the Eclipse addressing caudal migration. (OSOF ¶¶ 109). In short, the
 14 Eclipse was defective at the time it was sold.

15 Thus, Plaintiff’s claim for post-sale failure to recall and/or retrofit is analogous to
 16 the cases imposing a duty to warn of later discovered defects. As the *Ostendorf* court
 17 recognized, numerous cases impose a duty to warn of later discovered defects. *See,*
 18 *e.g., Gracyalny v. Westinghouse Elec. Corp.*, 723 F.2d 1311, 1318 (7th Cir. 1983)
 19 (manufacturer’s duty to warn extends to dangers that arise after marketing); *LaBelle v.*
 20 *McCauley Indus. Corp.*, 649 F.2d 46, 49 (1st Cir. 1981) (manufacturer’s duty to warn
 21 extends to purchaser even if defects are discovered after initial sale); *Chrysler Corp. v.*
 22 *Batten*, 264 Ga. 723, 450 S.E.2d 208, 211–13 (1994) (duty to warn arises whenever
 23 manufacturer knows or reasonably should know of danger arising from product use).
 24 When a product is defective, a manufacturer may be subject to one of these post-sale
 25 duties. The nature of the defect will dictate the appropriate remedy. A defect that may
 26 result in a few minor injuries may only require a warning, whereas a defect that may result
 27 in serious injury or death could require more. These remedial measures can be seen as “a
 28 continuum of post-sale duties which the law might impose....” *Gregory v. Cincinnati*

1 *Inc.*, 538 N.W.2d325, 341 (Mich. 1995) (Cavanagh, J., dissenting). Lastly, it is
 2 undisputed that the complications associated with the Eclipse device and its predecessors
 3 can result in life-threatening injury and death. As a result, there exists a genuine issue of
 4 material fact as to whether Bard breached a post-sale duty to recall the Eclipse, and
 5 Defendants' Motion should be denied.

6 **b. Bard undertook a retrofit campaign, and its negligent performance of**
 7 **this task increased the risk of harm to Ms. Mulkey.**

8 The Supreme Court of Kentucky has explained that a company undertaking a
 9 voluntary retrofit campaign can be liable if it performs its retrofit/recall campaign
 10 negligently, but only if the voluntary program induced reliance on the part of the plaintiff
 11 or other person. *Ostendorf*, 122 S.W.3d at 539 citing The Restatement (Second) of Torts
 12 § 324A (1965). The duty to retrofit is an example of a post-sale obligation which may be
 13 imposed on a manufacturer. *See id.* ("Other examples are duty to warn of later-discovered
 14 defects or foreseeable misuses *and the duty to recall a defective product*").

15 Bard undertook a voluntary retrofit campaign when it modified the predicate
 16 device, the G2X, to create the Eclipse Filter. When the Eclipse was marketed, Bard
 17 understood that its retrievable filter products had been a public health disaster, and that
 18 Bard needed to completely redesign its filter. (OSOF ¶ 103). Instead of pulling out of the
 19 retrievable filter market while fixing the design flaws, Bard created the Eclipse as nothing
 20 more than a re-branding of Bard's existing, defective filters. (OSOF ¶ 102, 105).

21 The modifications from the predicate device, the G2X, were minor. Bard changed
 22 the surface finish of the filter raw material wire by electropolishing the wire prior to
 23 forming the filter. Bard also made a cosmetic colorant modification to some of the
 24 molded components of the delivery kits. (OSOF ¶ 102, 108). Bard admitted that this
 25 minor design modification was added purely for marketing purposes and was not intended
 26 to overcome any of the serious complications of the prior Filter lines. (OSOF ¶ 102). A
 27 September 30, 2010 memorandum from Bard employee Brett Baird stated that the
 28 objective of the Eclipse was to "enhance the G2/X Filter surface finish through

1 electropolishing to bring it up to emerging industry standards and to improve the overall
2 fatigue resistance.” (OSOF ¶ 102). Yet Abithal Raji-Kubba, Bard’s Vice President of
3 Research and Development, confirmed that there was no evidence that the Eclipse
4 improved resistance to fracture, migration or corrosion. (OSOF ¶ 108). In reality, the
5 Eclipse Filter was similar to the G2/GX in just about every way. (OSOF ¶ 102, 108).

6 Nonetheless, Bard promoted the Eclipse as reducing the complications seen in prior
7 iterations. (OSOF ¶ 107). Enhancements were represented to doctors and patients as
8 reducing fracture, migration, tilt, and perforation and also as improvements over predicate
9 devices. (OSOF ¶ 101, 107). Bard sales promoted to doctors that the point of
10 electropolishing the Eclipse Filter was to reduce fracture. (OSOF ¶ 107). This feature
11 interested doctors. (OSOF ¶ 107). Bard undertook the task of retrofitting and improving
12 the G2X, thereby creating the Eclipse device. Bard acted negligently because, despite its
13 representations, Bard did not reduce the problems caused by the predicate devices. Bard
14 promoted the Eclipse as a safer product, so patients and physicians relied on these
15 representations, causing them harm. Kentucky law recognizes a claim for negligent
16 performance of a retrofit campaign under these facts. *See Ostendorf*, 122 S.W.3d at 538.

17 **VIII. MS. MULKEY’S CLAIM FOR NEGLIGENCE *PER SE* IS PROPER**
18 **BECAUSE IT IS BASED UPON VIOLATIONS OF THE KENTUCKY**
19 **CONSUMER PROTECTION ACT**

20 Bard argues that, under Kentucky law, a claim for negligence per se cannot be
21 based on violation of a federal statute or regulation. However, Ms. Mulkey’s negligence
22 *per se* claim is based upon Bard’s violations of a Kentucky statute, KRS § 367.110, *et seq.*
23 (the Kentucky Consumer Protection Act or “KCPA”), not a federal statute of regulation.
24 As detailed below, Ms. Mulkey has standing to bring a KCPA claim, although she did not
25 purchase the Eclipse filter directly from Bard, because Bard made express warranties for
26 the benefit of Kentucky consumers, including Ms. Mulkey.
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IX. MS. MULKEY HAS STANDING TO BRING A CLAIM UNDER THE KCPA BECAUSE BARD MADE EXPRESS WARRANTIES FOR THE BENEFIT OF KENTUCKY CONSUMERS.

Bard maintains that because Ms. Mulkey did not directly purchase the Eclipse filter from Bard, she is not in privity of contract and cannot maintain a KCPA claim. (Def. Mot. at 16). In many cases, privity of contract is required to maintain a private action under the KCPA. *Naiser v. Unilever U.S., Inc.*, 975 F. Supp. 2d 727, 743 (W.D. Ky. 2013) (citing *Ky. Laborers Dist. Council Health & Welfare Trust Fund v. Hill & Knowlton, Inc.*, 24 F. Supp. 2d 755, 772-73 (W.D. Ky. 1998)). But Kentucky courts recognize an exception to the privity requirement when express representations are alleged. *Naiser*, 975 F. Supp. 2d at 743–44; *Bosch v. Bayer Healthcare Pharmaceuticals, Inc.*, 13 F. Supp. 3d 730 (W.D. Ky. 2014). In this case, the privity requirement simply does not apply to Ms. Mulkey’s KCPA claims in light of the express representations and warranties made by Bard.

This issue has previously been decided by the Kentucky Court of Appeals. In *Skilcraft Sheetmetal, Inc. v. Ky. Mach., Inc.*, 836 S.W.2d 907, 909 (Ky. App. 1992), the court analyzed whether K.R.S. § 367.220 allows an action by a person who has not purchased or leased goods from the person he claims to have violated the KCPA. *Id.* The court held that a subsequent purchaser could not “maintain an action against a seller with whom he did not deal or who made no warranty for the benefit of the subsequent purchaser.” *Id.* (emphasis added). While privity is generally required to assert a cause of action under the KCPA, the court found certain situations “distinguishable ... such as that presented in *Ford Motor Co. v. Mayes*, *Ky.App.*, 575 S.W.2d 480 (1978), where the defendant (Ford Motor Company) provides warranties to the ultimate purchaser to repair the item purchased.” *Id.*

Notably, the United States District Court for the Western District of Kentucky focused on this language when deciding whether consumers in a putative class action against a hair product’s manufacturer had standing to assert a claim for violation of the KCPA. *See Naiser v. Unilever U.S., Inc.*, 975 F. Supp. 2d 727, 743 (W.D. Ky. 2013). In

1 *Naiser*, Plaintiffs relied on *Skilcraft* to argue that because the defendant manufacturer had
2 made express warranties for the benefit of Kentucky consumers, the plaintiffs had
3 standing to bring a KCPA cause of action. The court agreed. *See Id.*

4 As in *Naiser*, there is a genuine dispute of material fact as to whether Bard made
5 valid express warranties for the consumers' benefit. Bard expressly represented and
6 warranted that Bard IVC Filters were safe and effective for permanent implantation in the
7 human body. (OSOF ¶ 111-112). Bard represented that the Eclipse filter was an
8 improvement from the G2X filter. (OSOF ¶ 101). Bard sales promoted the Eclipse to be
9 more resistant to fracture and designed to be a permanent implant. (OSOF ¶¶ 101, 111-
10 112). Enhancements were represented to doctors and patients as reducing problems Bard
11 had seen—including fracture, migration, tilt, and perforation—and also as improvements
12 over predicate devices. (OSOF ¶ 101, 107). An Eclipse patient brochure stated: “The
13 Eclipse Filter does not have a time limit in which it must be removed. Your physician can
14 determine at which time it may be appropriate to have your Filter removed.” (OSOF ¶
15 112). Bard sales promoted to doctors that the point of electropolishing the Eclipse Filter
16 was to reduce fracture. (OSOF ¶ 107). Doctors were interested in this feature. (OSOF ¶
17 107). Bard breached its express warranties in that Bard IVC filters were improperly
18 designed resulting in an unreasonably high incidence of fracture, perforation of vessels
19 and organs, and/or migration, and they were not suitable for permanent implantation in the
20 human body. *See* discussion above. Moreover, as discussed above, despite Bard's
21 representations that the Eclipse filter was an improvement on, and safer than, the prior
22 iterations of the filter, Bard made no changes to the Eclipse filter that had any effect on
23 filter performance. (OSOF ¶¶ 102, 108). Therefore, the exception outlined in *Skilcraft*
24 *Sheetmetal* and *Naiser* applies, and Ms. Mulkey can maintain a KCPA claim against Bard
25 despite the absence of a direct buyer-seller relationship.

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X. CONCLUSION

Based on the foregoing, Bard's Motion for Summary Judgment should be DENIED.

RESPECTFULLY SUBMITTED this 2nd day of October 2017.

GALLAGHER & KENNEDY, P.A.

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CERTIFICATE OF SERVICE

I hereby certify that on this 2nd day of October 2017, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Deborah Yanazzo